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COMPLIANCE POLICY GUIDE

SUBSTITUTING ALBUTEROL HFA INHALERS FOR ALBUTEROL CFC INHALERS

BACKGROUND: The U.S. Food and Drug Administration (FDA) has published final rules to amend its regulation on the use of ozone-depleting substances (ODSs) in medical products. This rule states that as of December 31, 2008, production and sale of single ingredient albuterol chlorofluorocarbon (CFC) metered-dose inhalers (MDI) must cease.

GOAL: To provide a guide to pharmacists regarding substitution when refilling prescriptions written for albuterol MDIs.

POLICY:

1. If a pharmacy has a prescription with valid refills for an albuterol MDI that has been previously filled with a CFC product and the medical practitioner did not specify CFC on the prescription, the pharmacist may substitute a hydrofluoroalkane (HFA) MDI for the remaining refills without seeking permission of the medical practitioner, provided:

2. The pharmacist specifically counsels the patient about the change, including:

    a. The reason for the change, and

    b. Any differences the patient may experience.